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Original contribution

Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial

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ABSTRACT

Study objective: Several factors such as lack of unidirectional, turbulent free laminar airflow, duration of surgery, patient warming system, or the number of health professionals in the OR have been shown or suspected to increase the number of airborne bacteria. The objective of this study was to perform a multivariate analysis of bacterial counts in the OR in patients during minor orthopedic surgery.
Design: Prospective, randomized pilot study.
Setting: Medical University of Vienna, Austria.
Patients: Eighty patients undergoing minor orthopedic surgery were included in the study.
Interventions: Surgery took place in ORs with and without a unidirectional turbulent free laminar airflow system, patients were randomized to warming with a forced air or an electric warming system.
Measurement: The number of airborne bacteria was measured using sedimentation agar plates and nitrocellulose membranes at 6 standardized locations in the OR.
Main results: The results of the multivariate analysis showed, that the absence of unidirectional turbulent free laminar airflow and longer duration of surgery increased bacterial counts significantly. The type of patient warming system and the number of health professionals had no significant influence on bacterial counts on any sampling site.
Conclusion: ORs with unidirectional turbulent free laminar airflow, and a reduction of surgery time decreased the number of viable airborne bacteria. These factors may be particularly important in critical patients with a high risk for the development of surgical site infections.

1. Introduction

Surgical site infections (SSIs) are among the most severe complications in orthopedic and trauma surgery and have a serious impact on patient morbidity and mortality. Despite strict perioperative hygiene standards the incidence of postoperative orthopedic wound infections is still high ranging between 0.1% to 12% [1–3].

The infected surgical wound is usually colonized by commensal bacteria originating from the patient's own skin (endogenous) or exogenously by bacteria airborne in the operating room (OR). While there is general agreement on the protective effect of adequate skin antisepsis on the rate of SSIs, strategies to reduce airborne contamination are still disputed. One possibility for reducing airborne contamination is the use of a unidirectional turbulent free laminar airflow ventilation system (laminar airflow). Surprisingly, while the benefit of laminar airflow systems seems intuitive, evidence to implement laminar airflow as a standard requirement for every OR is contradictory [4,5]. As laminar airflow is costly and conclusive evidence is lacking, many hospital administrators hesitate to implement laminar airflow technologies in their ORs. In the US only 30% of 256 hospitals in 4 US states reported the regular use of laminar airflow in 2005 [6].

However, also other factors such as duration of surgery, number of OR staff [7] and use of forced air patient warming [8] might influence airborne bacterial displacement and could blur eventual beneficial effects of laminar airflow.

The aim of the study was thus to determine the influence of four intraoperative factors – use of laminar airflow, duration of surgery, number of health professionals present and use of forced air - on airborne bacterial contamination, measured by 6 sedimentation plates at standardized locations in the OR including two locations on the instrument table.

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Abbreviations

OR	Operating room
SSI	Surgical site infection
Laminar airflow	Laminar airflow ventilating system
CFU	Colony forming unit

2. Materials and methods

The study was approved by the Ethics Committee of the Medical University of Vienna and patients' written, informed consent was obtained in all patients undergoing minor orthopedic interventions either the day before surgery or on the day of surgery, if the patient had not been admitted to the hospital on the day before surgery, from January 2009 to June 2009. A manuscript using the same study patients' data as this paper demonstrated that different laminar airflow sizes affected the bacterial count on the instrument table [9]. In the present study bacterial counts on *all* positions were analyzed with multivariate methods, including the factor "patient warming system". Patients were randomized with excel random numbers to intraoperative warming with either a BairHugger forced air upper-body warming blanket (Arizant, Eden Prairie, MN) or a HotDog upper-body electric blanket (Augustine Biomedical + Design, Eden Prairie, MN) after induction of anesthesia. Randomization was performed by a medical student not involved with the study proceedings and delivered via opaque envelopes. Patients had to meet the following inclusion criteria: Age between 18 and 90 years, a BMI of 20–30, surgery lasting at least 1 h (expected).

A single observer (R.O.) present during each intervention monitored the following parameters: Number of health professionals present in the OR (maximum), duration of surgery (from skin incision to last suture), presence of a laminar airflow, and method of patient warming (forced air versus electric polymer blanket).

2.1. Measurements

Number of airborne bacteria was assessed by positioning four agar plates (90 mm diameter) in the OR and two nitrocellulose membranes (47 mm diameter) directly on the sterile instrument table. The first agar plate (plate 1) was positioned 15 cm above floor level, the second (plate 2) at table level, the third (plate 3) at 150 cm (plates 1–3 behind the surgical draping at the side of the anesthesiologist), and the fourth (plate 4) at table level with a distance of approximately 50 cm to the sterile operating field (on the surgical side of the draping). The nitrocellulose membranes (plates 5, 6) were both placed at the instrument table adjacent to each other (Fig. 2).

The agar plates and the nitrocellulose membranes were collected at the end of the surgical intervention. The nitrocellulose membranes were transferred to agar plates. All plates were then incubated for 48 h at 36°. After incubation the colony forming units (CFUs) were counted. The results were analyzed in CFU/m^2/h to adjust for OR size.

3. Statistical analysis

All values are displayed as means ± standard deviation, median (25th–75th quartile) or frequency (%), as appropriate. Plates 5 and 6 were averaged before analysis. Sample size was estimated with bacterial growth on the instrument table plates (mean of plates 5 & 6) as primary outcome. With an alpha error of 0.05, a power of 0.8 and an effect size of 0.7 for difference of airborne contamination by non-forced air warming versus forced air warming, 40 patients per group were calculated for a Wilcoxon-Mann-Whitney test as primary analysis. This simplified model was used to calculate the sample size estimate, since not enough previous knowledge about the possible relation of the main parameter of interest and airborne bacterial contamination was available.

Due to the skewed nature of bacterial growth data a generalized linear model with gamma distribution and log-link was used to analyze influence of time, number of health professionals, presence of laminar airflow and type of patient warming system on the number of viable bacteria at the different locations as secondary analysis. A QQ-Plot was performed to assess adequacy of assumption of distribution, which proved to be applicable.

G*Power (Duesseldorf, Germany) was used for sample size estimation; SPSS 23.0 (IBM, Armonk, NY, USA) was used for statistical analysis. A $p < 0.05$ was considered statistically significant.

4. Results

All patients completed the study. The average age of patients was 43 ± 15 years, with a weight of 78 ± 15 kg and a height of 174 ± 9 cm. 44 male (55%) and 36 female (45%) patients were included (see Fig. 1). Details about surgical interventions, number of health professionals present, duration of surgery, the use of forced air or electric blanket warming and laminar airflow are displayed in Table 1.

There was no difference for bacterial growth on the mean of plates 5 & 6 between the forced air and the non-forced air warming group ($p = 0.6$, Wilcoxon-Mann-Whitney test). Results of the multivariate model indicate, that a longer duration of surgery increased bacterial count on plates 1 to 4 and absence of laminar airflow increased bacterial count on plates 1 to 6 significantly (Table 2). There was a trend, that longer duration of surgery increased bacterial count on plates 5 & 6 ($p = 0.07$) as well. There was no difference for forced air versus resistive warming for bacterial count on either plate. A reduced model without patient warming method did not change any significances discovered in the extended model.

In a follow-up of all patients until hospital discharge (range 0–4 days), no SSIs were reported.

5. Discussion

In the present study we found, that the absence of laminar airflow and a longer duration of surgery increased airborne bacteria in the OR. In patients with a high risk for surgical wound infections, optimization of these factors may be an important preventive measure.

Despite being widely used the benefits of laminar airflow environments in ORs are still disputed. While the concept of clean, laminar flowing air to avoid SSIs is plausible and supported by some studies, other authors disagree as they were not able to demonstrate any beneficial effect of laminar airflow systems [4–6,10,11]. According to the present study other factors may be just as important as the availability of a laminar airflow system, e.g. a longer duration of surgery might completely annihilate the contamination-reducing effects of laminar airflow.

Particularly number of health professionals in the OR may be an important factor to consider when reducing airborne contamination, [7] however this effect could not be reproduced in our study, possibly due to the limited number of patients.

As mentioned the duration of surgery is in our study a very influential factor determining the amount of bacterial sedimentation. However, this factor itself obviously is dependent again on a number of other factors, which may not all be equally optimizable: the skill of the surgeon, type of surgery, OR management, patient's surgical site and others [12, 13].

An important finding of our study was that the type of patient warming did not influence the amount of bacterial sedimentation on either plate position. It is important to remember, that the introduction of an efficient forced-air patient warming system initially led to a major decrease in wound infections, which had a higher incidence in un-

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

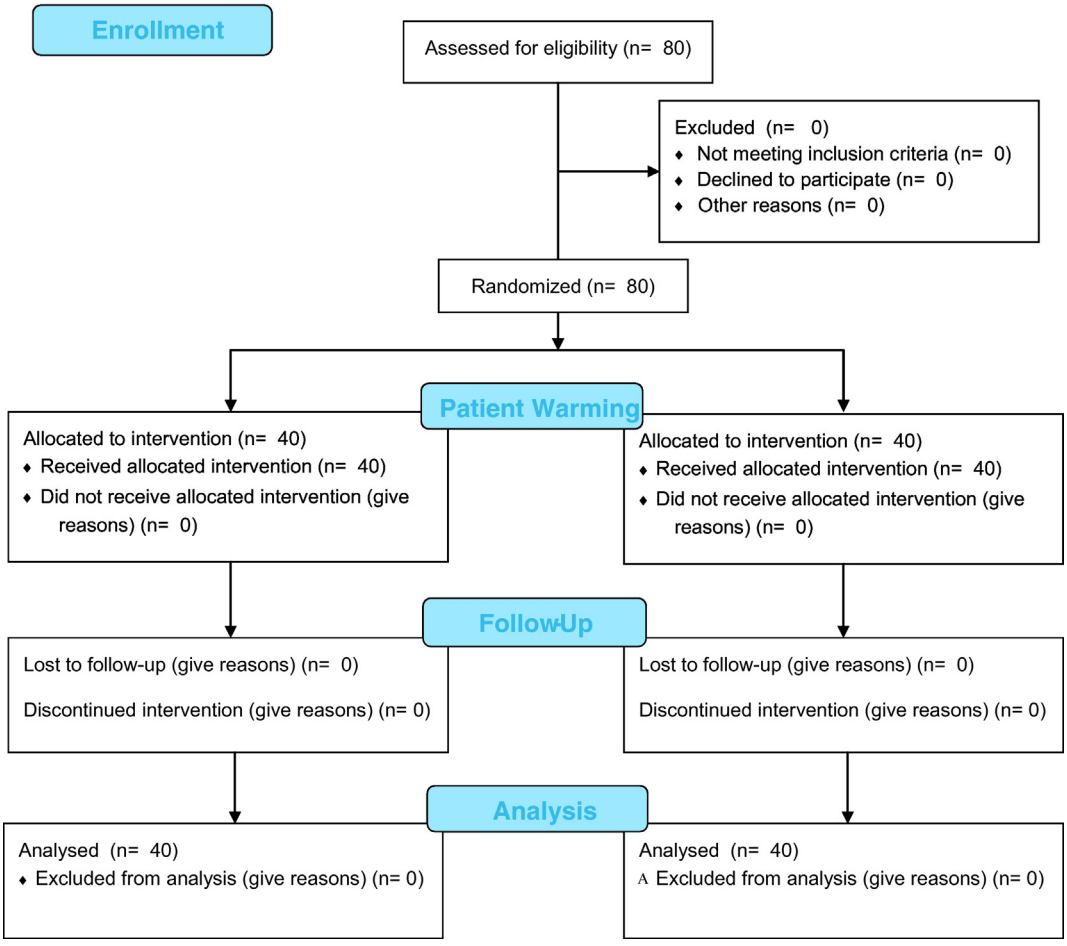

Fig. 1. Consort flow diagram.

warmed patients with accidental perioperative hypothermia [14]. Evidence for the many beneficial effects of perioperative normothermia is undeniably fully established. However, over the last years there has been a lively discussion if the air from forced air warming devices might directly distribute bacteria originating from the environment or the inside of the device into the sterile field in clinically relevant amounts, as micro-organisms have been detected in such warming devices and in the air coming from those devices [15–18].

Table 1
Demographic data, type of surgery, number of health professionals, duration of surgery by patient warming method and use of laminar airflow.

	Forced air (n = 40)		Electric blanket (n = 40)	
	Laminar flow (n = 20)	No laminar flow (n = 20)	Laminar flow (n = 20)	No laminar flow (n = 20)
Age of patients (years)	42 ± 20	48 ± 12	36 ± 8	45 ± 15
Gender of patient (male/female)	10/10	12/8	14/6	7/13
Surgery (%, mean duration in min ± SD; p = 0.13, chi square test)				
Athroscopy of knee, shoulder and wrist joint (51.48 ± 11.0 min)	55%	35%	70%	55%
Osteosynthesis (47.08 ± 11.96 min)	25%	20%	15%	5%
Metal implant removal (47.50 ± 15.00 min)	0%	20%	5%	5%
Surgery of ligaments and of soft tissue (45.00 ± 13.28 min)	15%	25%	10%	35%
Total knee replacement (60 min)	5%	0%	0%	0%
Number of health professionals	9 (7–12)	7 (5–9)	9 (6–12)	7 (5–9)
Duration of surgery (min)	57 ± 7	40 ± 10	56 ± 7	43 ± 12

Duration of surgery: mean ± SD, number of health professionals: median [range], surgery: frequency (% of all interventions, n = 80).

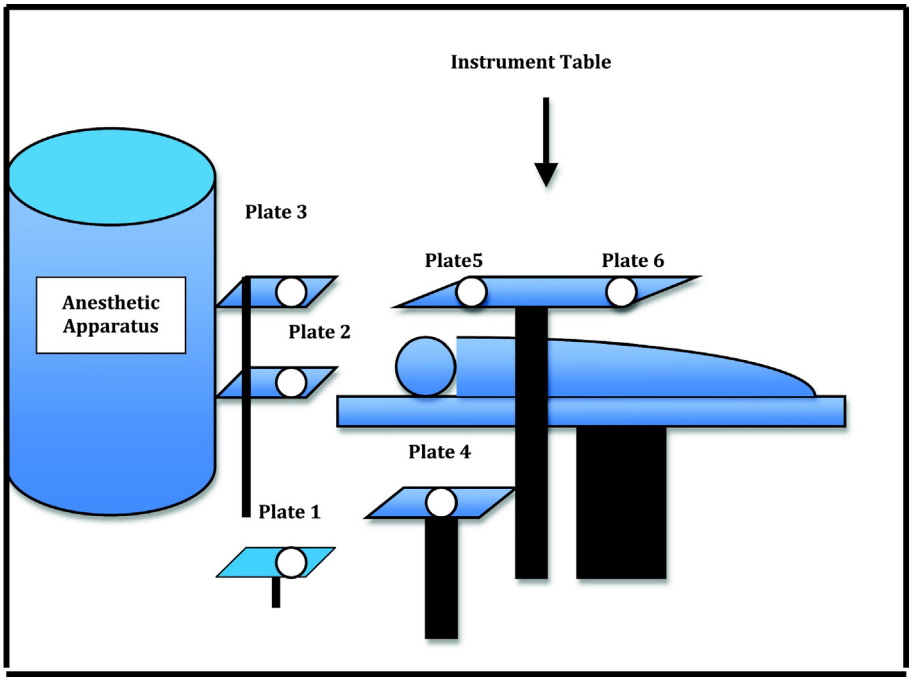

Fig. 2. Positioning of agar plates during the study – plate 1 was positioned 15 cm above floor level, plate 2 at table level, plate 3 at 150 cm, plate 4 at table level with a distance of approximately 50 cm to the sterile operating field. The nitrocellulose membranes (plates 5, 6) were both placed at the sterile instrument table adjacent to each other.

Another focus of this discussion was on the disruption of laminar airflow by forced air blowers, which was confirmed by some studies [19–22] and rebutted by others [23–26].

In our study it was not possible to detect any higher bacterial counts on any plate in the forced air warming group versus the resistive warming group. The study may obviously not be generalized for an overall safety statement on forced air warming, and is primarily applicable in the particular surgical setup. However – with class action lawsuits "judging" the scientific question of forced air safety with unsuitable, i.e. legal, means subsequent studies are all the more warranted. Only a large, randomized, controlled trial of forced air warming versus non-forced air warming will help to decide, if patient outcome is influenced by the use of forced-air devices. Until this study has been performed, the hypothesized risks of forced air warming remain unclear. With a multitude of factors influencing a patient's risk for perioperative infection, only this kind of study will be able to answer the question, if forced air warming is a major influence on surgical wound contamination, whose voice can be reliably detected in the large choir of all the other factors, such as transmission via the anesthesiologist's [27] or surgeons hand, [28] skin preparation, sterile surgical technique, duration of surgery, surgical skill, patient-related risk factors such as obesity, diabetes mellitus or pre-existing colonization and inadequate antibiotic treatment [29] among many others.

The present study has several limitations. Surgery was primarily minor orthopedic surgery. Unsurprisingly, in the present study no SSIs occurred. However, a study with SSI as endpoint would have required a much larger setup, since SSIs are rare in the study's particular patient population. The upper-body position of the forced-air warming system in relation to the sterile field on the lower body may have reduced the effect of forced air warming turbulence on airborne contamination in the sterile field. Only the maximum number of health professionals present was recorded in the present study. A more elaborate approach has recently been presented by Masursky et al. [30] However, since the surgeries were not very complex and their duration was relatively short, changes of number of health professionals during surgery was a rare occurrence. Furthermore, the factor "laminar flow" could not be randomized, since OR assignment could not be changed for study purposes. Finally, incidences of opening and closing of doors were not recorded – as the operating theatres are protected by an airlock system, the impact of this factor may not be a major influence.

In conclusion, the present study shows that in the setting of minor orthopedic surgery an OR with laminar airflow, a reduction of surgery time, by trend a reduced number of personnel present, but not the choice of a non-forced air patient warming system was associated with a decreased airborne sedimentation. Optimizing these factors in critical patients with a high risk for the development of SSI may allow further reduction in the incidence of SSIs. As far as forced air warming is concerned subsequent large, randomized controlled patient studies are highly commended to allow evidence based conclusions regarding any influence of forced air warming on perioperative outcome.

Table 2
Results of a multivariate analysis of factors influencing bacterial deposition (generalized linear model with gamma distribution and log link, exp (B) and 95% Wald confidence intervals in brackets).

	Plate 1	Plate 2	Plate 3	Plate 4	Plate 5 & 6
Absence of laminar flow	2.42 (1.00–5.83)*	3.70 (2.05–6.67)#	3.48 (1.61–7.51)*	5.10 (2.59–10.06)#	2.18 (1.13–4.20)*
Presence of forced air warming	1.13 (0.74–1.71)	1.07 (0.70–1.65)	1.30 (0.7–2.38)	1.55 (0.92–2.60)	1.00 (0.56–1.80)
Duration (min)	1.05 (1.02–1.07)#	1.03 (1.01–1.05)*	1.05 (1.02–1.07)#	1.05 (1.03–1.07)#	1.02 (1.00–1.05)+
Number of health professionals in OR (5–12)	0.92 (0.72–1.17)	1.05 (0.93–1.20)	1.04 (0.80–1.35)	1.11 (0,90–1.37)	0.86 (0.66–1.11)

+ $p = 0.07$.
* $p \leq 0.05$.
# $p < 0.001$.

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Conflict of interest

Oliver Kimberger has received financial support for studies and travel costs and fees for speaker assignments from the following companies producing patient temperature management products: Biegler GmbH, Mauerbach, Austria; Augustine Biomedical, Eden Prairie, MN, USA; Möck&Möck, Hamburg, Germany; Zoll, USA; Zoll, San Jose, CA, USA; 3 M, St. Paul, MN, USA; Dräger AG, Lübeck, Germany; 3M, St. Paul, MN, USA; The 37 Company, Amersfoort, the Netherlands.

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